

Food and Drug Administration Silver Spring, MD 20993

Sam Boddapati, PhD Sr. Vice President, Regulatory Affairs Oak Pharmaceuticals, Inc. 1925 West Field Court, Suite 300 Lake Forest, IL 60045

RE: ANDA 083246

Nembutal Sodium Solution (pentobarbital sodium injection, USP) CII MA #20

Dear Dr. Boddapati:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed a Booth Graphic 48x60 Vinyl banner (exhibit banner) for Nembutal Sodium Solution (pentobarbital sodium injection, USP) CII (Nembutal) submitted by Oak Pharmaceuticals, Inc. (a subsidiary of Akorn, Incorporated)(Oak) under cover of Form FDA-2253. The exhibit banner was displayed at the American Society of Health-System Pharmacists (ASHP) Meeting held in Anaheim, CA on December 7-11, 2014, and viewed by two OPDP representatives. The exhibit banner is misleading because it omits important risk information associated with the use of Nembutal and omits material facts. Thus, the exhibit banner misbrands Nembutal within the meaning of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and makes its distribution violative. 21 U.S.C. 352(a); 321(n); 331(a); 21 CFR 1.21(a). *Cf.* 21 CFR 202.1(e)(5).

Background

Below are the indication (in pertinent part) and summary of the most serious and most common risks associated with the use of Nembutal.¹

According to the INDICATIONS AND USAGE section of the FDA-approved product labeling (PI), Nembutal is indicated for use as an anticonvulsant, in anesthetic doses, in the emergency control of certain acute convulsive episodes, e.g., those associated with status epilepticus, cholera, eclampsia, meningitis, tetanus, and toxic reactions to strychnine or local anesthetics.

Nembutal is contraindicated in patients with known barbiturate hypersensitivity or a history of manifest or latent porphyria. The PI for Nembutal contains warnings and precautions regarding the potential to be habit forming, IV administration, acute or chronic pain, use in pregnancy, synergistic effects, and central nervous system (CNS) depressant effects. The most common adverse reaction is somnolence.

Reference ID: 3756094

¹ This information is for background purposes only and does not necessarily represent the risk information that should be included in the promotional piece cited in this letter.

Omission of Risk Information

Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials.

The exhibit banner includes claims such as, "Control the Uncontrollable" and "the control you need when seizures are their worst;" however, it omits **all** of the contraindications, warnings and precautions, and common adverse reactions associated with the use of Nembutal. By failing to present any risk information associated with Nembutal, the exhibit banner misleadingly suggests that Nembutal is safer than has been demonstrated. We note that the statement "SEE BOOTH REPRESENTATIVE FOR FULL PRESCRIBING INFORMATION AND IMPORTANT SAFETY INFORMATION" is included at the bottom of the exhibit banner. However, this statement does not mitigate the misleading omission of risk information.

Omission of Material Facts

The exhibit banner makes representations about the use of Nembutal for the treatment of seizures, but it is misleading because it fails to communicate material information regarding the FDA-approved indication for Nembutal. Specifically, it omits the following material information from the INDICATIONS AND USAGE section of the PI (in pertinent part, emphasis added):

Anticonvulsant, in anesthetic doses, in the emergency control of certain acute, convulsive episodes, e.g., those associated with status epilepticus, cholera, eclampsia, meningitis, tetanus, and toxic reactions to strychnine or local anesthetics.

Conclusion and Requested Action

For the reasons discussed above, the exhibit banner misbrands Nembutal within the meaning of the FD&C Act, and makes its distribution violative. 21 U.S.C. 352(a); 321(n); 331(a); 21 CFR 1.21(a). *Cf.* 21 CFR 202.1(e)(5). OPDP requests that Oak immediately cease misbranding Nembutal. Please submit a written response to this letter on or before May 29, 2015, stating whether you intend to comply with this request, listing all promotional materials (with the 2253 submission date) for Nembutal that contain presentations such as those described above, and explaining your plan for discontinuing use of such materials.

Please direct your response to the undersigned at the Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266 or by facsimile at (301) 847-8444. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA # 20 in addition to the ANDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. OPDP reminds you that only written communications are considered official.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your distribution of Nembutal complies with each applicable requirement of the FD&C Act and FDA implementing regulations.

Sincerely,

{See appended electronic signature page}

Melinda McLawhorn, PharmD, BCPS, RAC Acting Team Leader Office of Prescription Drug Promotion

{See appended electronic signature page}

Mathilda Fienkeng, PharmD, RAC Team Leader Office of Prescription Drug Promotion This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MELINDA W MCLAWHORN
05/14/2015

MATHILDA K FIENKENG
05/14/2015